OCT 1 8 2002

K023249

Abbreviated 510(k) Summary
Alcon LADARWave™ CustomCornea® Wavefront System

I. General Information

a. Applicant: Alcon
2501 Discovery Drive, Suite 500
Orlando FL 32826

b. Contact Person: Christy Stevens, OD

c. Telephone: (407) 384-1600
Fax: (407) 384-1699

d. Summary Preparation Date: September 27, 2002

II. Names

Device Name: Alcon LADARWave™ CustomCornea® Wavefront System
Primary Classification Name: Ophthalmic Diagnostic Device Refractometer
Class I 886.1760

III. Predicate Devices

Predicate Devices: As defined in the 21 CFR Sections 886.1350, 1760, 1770, and 1780, there are several diagnostic devices employed to measure the refractive power and any refractive errors of the eye. Some measure the corneal curvature (MMQ, HJA, 886.1350), some measure the refractive power of the eye by measuring light reflexes from the retina (HKO, 886.1760), some use lenses and subjective responses from the subject being measured (HKN, 886.1770) and some illuminate the retina and note the direction of movement of the light on the retinal surface to determine the refraction by the eye of the emergent rays (HKL, 886.1780). Each of these diagnostic devices provides some valuable information in assessing the refractive errors of the ocular system. However, no one product is available to date which is able to provide a comprehensive assessment of refractive errors.

The LADARWave™ CustomCornea® Wavefront System has the following characteristics in common with other refractive diagnostic device products:

- Each of the diagnostic devices, which serve as predicates to this device, measure refractive characteristics of the eye.
- Each of the diagnostic approaches operates on a similar principle of using some form of light energy reflected off an ocular structure (cornea, retina), which is then documented to communicate the degree from which the eye deviates from normal.
- Each of the diagnostic devices used to assess refractive errors of the eye pose **no significant risk** to the patient.

The LADARWave™ CustomCornea® Wavefront System is substantially equivalent to prior aberrometers and the predicate model approved under K000637.

IV. Product Description

The LADARWave™ CustomCornea® Wavefront System is an aberrometer, utilizing Hartmann-Shack wavefront sensing to measure the aberrations in the human eye. The device contains four major optical subsystems used in the clinical wavefront examination.

- A fixation subsystem provides the patient with an unambiguous point of fixation. Optics in this path adjust automatically to correct for the patient's spherocylindrical error so that the target is clearly observed.
- A video subsystem provides the device operator with a view of the eye at the measurement plane. The operator uses the video imagery to position the eye for the measurement and to record the geometry of the wavefront relative to anatomical features.
- A probe beam subsystem directs a narrow beam of eye-safe infrared radiation into the eye to generate the re-emitted wavefront.
- A wavefront detection subsystem images the re-emitted wavefront onto the entrance face of the Hartmann-Shack wavefront sensor.

These subsystems are all under control of the device software.

V. Indications for Use

The LADARWave™ CustomCornea® Wavefront System is used for measuring, recording, and analyzing visual aberrations (such as myopia, hyperopia, astigmatism, coma and spherical aberration) and for displaying refractive error maps of the eye to assist in prescribing refractive corrections. This device is enabled to export wavefront data and associated anatomical registration information to a compatible treatment laser with an indication for wavefront-guided refractive surgery.

VI. Rationale for Substantial Equivalence

The LADARWave™ CustomCornea® Wavefront System shares the same indication for use and similar design features as the predicate devices.

VII. Conclusion

The LADARWave™ CustomCornea® Wavefront System is substantially equivalent to currently marketed aberrometers. The LADARWave™ CustomCornea® Wavefront System shares the same intended use and indication for use and other basic system characteristics as the predicate systems. This device is enabled to export wavefront data and associated anatomical registration information to a compatible treatment laser with an indication for wavefront-guided refractive surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alcon Laboratories, Inc.
c/o Christy Stevens, OD
Director Clinical Affairs
2501 Discovery Drive, Suite 500
Orlando, FL 32826

OCT 18 2002

Re: K023249
Trade/Device Name: Alcon LADARWave™ CustomCornea® Wavefront System
Regulation Number: 21 CFR 886.1760
Regulation Name: Ophthalmic Refractometer
Regulatory Class: Class I
Product Code: NCF
Dated: September 27, 2002
Received: September 30, 2002

Dear Dr. Stevens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address. http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use Statement

510(k) Number (if known): K023249

Device Name: Alcon LADARWave™ CustomCornea® Wavefront System

Indications for Use: The LADARWave™ CustomCornea® Wavefront System is used for measuring, recording, and analyzing visual aberrations (such as myopia, hyperopia, astigmatism, coma and spherical aberration) and for displaying refractive error maps of the eye to assist in prescribing refractive corrections.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: X Or Over the Counter Use: _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K023249

Optional Format 1-2-96